510(k) SUMMARY- IC-PRO System

MAY 2 7 2011

Submitter Name:	Paieon Inc.
Submitter Address:	747 Third Ave., 4th floor New York, NY 10017-2803
Contact Person:	Erez Ben-Zvi
Phone Number:	+972 3 915 0000
Fax Number:	+972 3 901 2324
Date Prepared:	January 23, 2011
Device Trade Name:	The IC-PRO System
Device Common Name:	Cardiovascular Angiography Analysis System
Classification Name:	Angiographic x-ray system
Predicate Devices:	The IC-PRO (version 3.2) System cleared under K083745; The Integris 3D-RA system cleared for marketing under K040254; The Vitrea 2 medical image processing software cleared under K040305. The iConnection PRO Stent Positioning System cleared under K040876;
Device Description:	The IC-PRO (version 3.5, model B) system is an image acquisition and processing modular software package designed as an add-on to conventional X-ray angiography systems. This system improves the output of cardiovascular angiography by providing software modules that assist in diagnosis, procedure planning, therapeutic stage and post deployment analysis. The IC-PRO provides quantitative data and vessel measurements, left ventricular, stent dimensions, enhances visualization, localizes device on predefined roadmaps and assist in projection selection. The IC-PRO is used in patient with vascular, congenital, valvular, and myopathic heart disease and patients undergoing vascular stenting and artificial valve deployment.

Intended Use:

IC-PRO, an image acquisition and processing modular software package, is indicated for use as follows:

- Assists in the evaluation of coronary lesions by enabling the creation of 3D images of coronary vessel segments based on two to three 2D angiography images obtained from single plane angiography. Provides quantitative information regarding the calculated dimensions of arterial segments based on the 3D image.
- Performs quantitative analysis of the left ventricle based on left ventricular angiograms.
- Enhances visualization of the stent deployment region and provides quantitative data based on manual stent tracings
- Assist in device positioning by providing real time localization on predefined roadmaps.
- Assists in projection selection using 3D modeling based on 2D images.
- Performs dimensional measurements based on DICOM images.
- To be used in-procedure in the catheterization lab and off-line for post-procedural analysis

It is intended for use by clinicians, technicians and research personnel.

Performance Standards: None

Performance Data: Testing included software validation and performance evaluation. The performance tests were made to evaluate the IC-PRO System and yield accuracy and precision results within the predetermined specifications.

Substantial Equivalence: The intended use and technological characteristics of the IC-PRO (version 3.5, model B) are substantially equivalent to a combination of the intended use, technological characteristics of the predicate devices and human factors.
All IC-PRO modules but the projection selection modules are identical in terms of intended use and functionality and similar to the specifications of the cleared IC-PRO (version 3.2).
The Projection selection module is similar in terms of indication for use, intended use, technical characteristics and output to the rest of the predicate devices.
All predicate devices are image processing software enabling working with DICOM XA imaging format.
All found differences raise no new safety and effectiveness issues

Conclusion: The testing reported in this 510(K) establishes that IC-PRO is substantially equivalent to the predicate devices and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Paieon, Inc.
% Mr. Erez Ben-zvi
Official Correspondent
Paieion Medical Ltd.
23 Hamelacha St., P.O.B. 11355
Rosh Haayin, 48091
ISRAEL

MAY 2 7 2011

Re: K110256
Trade/Device Name: The IC-PRO System
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI and LLZ
Dated: April 6, 2011
Received: April 11, 2011

Dear Mr. Ben-zvi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

Device Name: **The IC-PRO System**

Indications for Use:

IC-PRO, an image acquisition and processing modular software package, is indicated for use as follows:

- Assists in the evaluation of coronary lesions by enabling the creation of 3D images of coronary vessel segments based on two to three 2D angiography images obtained from single plane angiography. Provides quantitative information regarding the calculated dimensions of arterial segments based on the 3D image.
- Performs quantitative analysis of the left ventricle based on left ventricular angiograms.
- Enhances visualization of the stent deployment region and provides quantitative data based on manual stent tracings
- Assist in device positioning by providing real time localization on predefined roadmaps.
- Assists in projection selection using 3D modeling based on 2D images.
- Performs dimensional measurement on DICOM image.
- To be used in-procedure in the catheterization lab and off-line for post-procedural analysis

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110256